

POST-MASTER'S CERTIFICATE in BIOPHARMACEUTICAL MANUFACTURING AND REGULATORY AFFAIRS

Pharmaceutical biotechnology development, manufacture, and distribution

BACKGROUND

Ever since the first biopharmaceutical product (recombinant human insulin) was approved in 1982, products derived through biotechnology have provided medical advances that include therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors.

The regulatory framework required for the approval of biotechnology-derived products (or biologics) is lengthy, rigorous, and highly complicated. Temple's *Post Master's Certificate in Biopharmaceutical Manufacturing and Regulatory Affairs (RA)* focuses on the complex regulations governing the development, manufacture, and distribution of these products, preparing students for positions in biotechnology and sharpening the skills and knowledge of those already working in this field.

This certificate presents a strong regulatory focus, enabling students to become fluent in the most current regulations and trends affecting the industry. Current pharmaceutical science methods used in the discovery of biotechnology products are studied, including materials sourcing and testing requirements. Technologies and unique considerations associated with the manufacturing and distribution of biotechnology products are discussed, along with the regulatory requirements for sterilization processes, whether thermal, gaseous, radiation, or filtration, as well as aseptic processing.

Faculty are drawn from the FDA and the biotechnology industry, assuring that the latest developments and practices are taught. These are industry and regulatory veterans with years of expertise in their specialties, sharing their considerable knowledge with students through intimate classroom discussions and hands-on workshops.

The biotechnology industry continues to offer the largest number of new job opportunities in the U.S. and abroad. While the two largest hubs for biotechnology are Boston and San Francisco, accounting for over 50,000 jobs in pharmaceutical biotechnology discovery and development, hundreds of small, start-up biotechnology companies exist throughout the U.S. All courses in the *Post Master's Certificate Biopharmaceutical Manufacturing and RA* are offered online, allowing remote students to participate in this highly relevant program.

For nearly five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. The School was the first institution of higher learning in the U.S. to create a master's program in the Quality Assurance (QA) and Regulatory Affairs

(RA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's renowned program specifically examines RA and QA issues facing the medical device, biotechnology, pharmaceutical and related industries. Courses discuss current practices and issues in device, biotechnology, and pharmaceutical law and regulation, technology, and quality assurance practices.

Temple's RAQA graduate program is based in Fort Washington, PA. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals. More than 60 courses are offered online.

To receive the Post-Master's certificate, candidates must hold a master's degree in the sciences and complete the required courses and application procedures.

APPLICATION PROCESS

Temple University Students:

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA*, you must formally apply, so we can reopen your file to register you. The application is available on the Certificates link of the RAQA homepage: (www.temple.edu/pharmacy_QARA).

You will be required to take four courses relating to Biopharmaceutical Manufacturing and RA to complete the Post Master's Certificate in this subject. One must be Pharmaceutical Biotechnology (8005), unless you previously took that course while you were pursuing the MS in RAQA.

Please mail the application to:

Temple University School of Pharmacy
RAQA Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

Students with Advanced Science Degrees from Other Schools:

To apply for the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA*, you must meet the following criteria:

- 1) You must have received an advanced degree (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.
- 2) Please write a letter to the Assistant Dean (Temple University RAQA Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. Include the Application for the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA*, a copy of your resume, and copies

of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA* must be received from the Assistant Dean before commencing any courses in the program.

- 3) Students with advanced degrees from other schools will be required to take five Temple University RAQA courses to receive the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA*. If the candidate subsequently decides to apply for the M.S. in Regulatory Affairs and Quality Assurance within five years, the credits earned in the *Post-Master's Certificate in Biopharmaceutical Manufacturing and RA* will count towards the master's degree, provided a grade of B or higher is earned in each course and the student is accepted into the M.S. program.

TO RECEIVE THE CERTIFICATE

After you have finished the required courses, fill out the Notice of Completion (available on the RAQA website) and forward it to the RAQA Office by fax (267.468.8565), email (qarareg@temple.edu), or hard copy.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the RAQA Office **at least one month in advance**. Otherwise you will have to wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the Advanced Certificate.

Courses Accepted for the Post-Master's Certificate in Biopharmaceutical Manufacturing and RA

To earn the certificate, four (for Temple U RAQA graduates) or five courses (for students with other advanced degrees) must be successfully completed within a four year period with an overall B (3.0) average:

- **Biotechnology: Bioprocess Basics** (5471)*
- **Production of Sterile Products** (5492)
- **Sterilization Processes** (5493)
- **Development of Sterile Products** (5501)
- **Microbiological Concepts in Pharmaceutical Manufacturing** (5512)*
- **Biologics/ Biosimilars: A Regulatory Overview** (5515)*
- **Vaccines: RA and QA Issues** (5572)
- **Regulatory Bioanalysis** (5621)
- **Pharmaceutical Biotechnology** (8005)*

*Students must take these courses, if they have not already done so.

QUESTIONS AND ANSWERS

Where is Temple's RAQA program offered?

Temple University's RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, refer to our website:

http://www.temple.edu/pharmacy_QARA/map.htm

Courses can also be videoconferenced to corporate sites. Over 60 courses are available online in real-time. The *Post Master's Certificate in Biopharmaceutical Manufacturing and RA* is offered entirely online.

When can I start the program?

Courses in the RAQA program are offered during the fall, spring and summer semesters every year. You may start the certificate program at your convenience.

What course sequence is recommended?

Courses may be taken in any order. Students must take the courses marked with asterisks above, if they have not previously completed them as part of the MS in RAQA.

The RAQA program offers over 80 different courses, which are rotated over a 2 to 3 year period. Courses are not necessarily offered every semester. We urge students to take courses when they are scheduled or to write to the RAQA Office if they wish to see a course scheduled in a particular semester.

How do I obtain a current class schedule?

Please check the RAQA homepage: **www.temple.edu/pharmacy_QARA**

How do I register for classes?

You must be formally admitted to the *Post-Master's Certificate in Biopharmaceutical Manufacturing and RA* before registering for any courses.

- If you received your MS from Temple, download the registration form from the RAQA homepage; http://www.temple.edu/pharmacy_QARA/forms.htm
You do not need to submit a state residency form, unless you have moved from one state to another.
- If you have not registered for Temple University RAQA courses before, download the Registration and State Residency forms from the RAQA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm
Both are required the first time you register. Fax, mail, and online registrations do not guarantee your spot in a class, since sections do fill quickly. You will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

Do I need to submit GRE scores to complete the certificate?

No. GRE scores are not required for this certificate or for the MS in RAQA.

Can I complete the *Post-Master's Certificate in Pharmaceutical Manufacturing and RA* and apply the credits towards the MS in RAQA?

Yes. The MS in RAQA has an entirely different application process. For additional information on the Master of Science in Regulatory Affairs and Quality Assurance, please request a Program Guide and an application form by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Post Master's Certificate in Biopharmaceutical Manufacturing and RA*?

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA graduate program. If you have taken identical or very similar courses at another institution, you may request to take an alternate course in its place.

Will the Certificate automatically be awarded when I complete the required courses?

No. When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office via fax (267.468.8565) by the stipulated deadlines (Jan 15, May 15, or Aug 20). Otherwise you will have to wait until the next time they are processed.

Is there a deadline for completing the courses?

You should complete the *Post-Master's Certificate in Pharmaceutical Manufacturing and RA* within four years. If you need an extension, please email gara@temple.edu.

Will new electives be added to the certificate program?

Yes. The RAQA program continues to expand its curriculum. For a listing of current courses, please consult the RAQA website.

**For additional information:
RAQA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19034**

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E-mail: QARA@temple.edu
www.temple.edu/pharmacy_QARA**